

## ESI Qual International

968 Washington St., 2nd Floor

Stoughton, MA 02072

(781) 344-6344

Fax (781) 341-3978

E-mail [info@esigual.com](mailto:info@esigual.com)

0976 '00 DEC 13

December 7, 2000

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: DOCKET NUMBER 00D-1555

This Draft Guidance would create undue hardship on Seafood Processors with limited storage space on-site.

The issue was discussed during the development of the Seafood HACCP Regulation and it was decided the Agency would allow a reasonable time for a processor to produce archived records.

An article in Food Chemical News' HACCP Newsletter indicated the agency is clarifying its policy because processors in one country refused to allow inspections. That is hardly an appropriate response if in fact the article is correct.

The existing regulation contains provisions to deal with inspection refusals: product from processors without HACCP Plans, or from processors who fail to make records available, or from processors who refuse inspections, is considered to be adulterated. That product and processor can be placed on an automatic detention list. It should never see a US market.

Further, the Agency says it is 'clarifying' the regulation. It appears the Agency is modifying the regulation from 'producing records for review within a reasonable time' to 'requiring records to be stored on-site'.

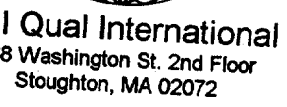
The Agency should not 'clarify' or modify the existing regulation with respect to record storage and availability. The Agency should instead take appropriate (and parallel) action against domestic and foreign processors who fail to allow inspection.

Sincerely,

Phil Ventresca, CQA-HACCP  
President

00D-1555

CI



U.S. POSTAGE  
0.033

H METER 174525

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
|||||

20457-0001

